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Endoscopic Laser Photocoagulation in the Treatment of Upper Gastrointestinal Bleeding

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FOREWORD

The Office of Health Technology Assessment (OHTA) evaluates the safety and effectiveness of new or unestablished medical technologies that are being considered for coverage under Medicare. These assessments are performed at the request of the Health Care Financing Administration (HCFA). They are the basis for recommendations to HCFA regarding coverage policy decisions under Medicare.

Questions about Medicare coverage for certain health care technologies are directed to HCFA by such interested parties as insurers, manufacturers, Medicare contractors, and practitioners. Those questions of a medical, scientific, or technical nature are formally referred to OHTA for assessment.

OHTA's assessment process includes a comprehensive review of the medical literature and emphasizes broad and open participation from within and outside the Federal Government. A range of expert advice is obtained by widely publicizing the plans for conducting the assessment through publication of an announcement in the Federal Register and solicitation of input from Federal agencies, medical specialty societies, insurers, and manufacturers. The involvement of these experts helps assure inclusion of the experienced and varying viewpoints needed to round out the data derived from individual scientific studies in the medical literature. After OHTA receives information from experts and the scientific literature, the results are analyzed and synthesized into an assessment report. Each report represents a detailed analysis of the safety, clinical effectiveness, and uses of new or unestablished medical technologies considered for Medicare coverage. These Health Technology Assessment Reports form the basis for the Public Health Service recommendations to HCFA and are disseminated widely.

Individual reports are available to the public once HCFA has made a coverage decision regarding the subject technology. OHTA also publishes compilations that contain all assessment reports submitted to HCFA in a given calendar year.

OHTA is part of the National Center for Health Services Research and Health Care Technology Assessment (NCHSR), Public Health Service, Department of Health and Human Services.

Enrique D. Carter, M.D.
Director, Office of Health
Technology Assessment

J. Michael Fitzmaurice, Ph.D.
Director, National Center for
Health Services Research and
Health Care Technology Assessment

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Publications and Information Branch
NCHSR
Parklawn Building, Room 18-12
5600 Fishers Lane
Rockville, MD 20857; (301) 443-4100

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ABSTRACT

Endoscopic laser photocoagulation for the treatment of upper gastrointestinal bleeding involves the application of laser light to a bleeding lesion through a fiberoptic endoscope which is introduced into the gastrointestinal tract orally. Laser catheters are advanced through the endoscope and are aimed at the bleeding lesion. The most frequently used laser is Neodynium YAG, (Nd:YAG) although argon and other forms are also used. Eighty percent of people with massive upper gastrointestinal hemorrhage cease bleeding spontaneously; those who do not may require surgery, laser photocoagulation, or other interventions to achieve hemostasis. While the results of controlled trials have been mixed, existing experience with laser photocoagulation use by trained individuals in controlled environments has proven beneficial in treating UGI hemorrhage. At present, a drawback to the use of the laser is its lack of portability. Laser-induced bleeding remains a concern.

PUBLIC HEALTH SERVICE ASSESSMENT
ENDOSCOPIC LASER PHOTOCOAGULATION IN THE TREATMENT OF UPPER GASTROINTESTINAL BLEEDING

1987

Endoscopic laser photocoagulation for the treatment of upper gastrointestinal (UGI) bleeding involves the application of laser light to a bleeding lesion through an optical fiber passed to the gut via a channel of a flexible endoscope. The most frequently used instrument is the Nd-YAG laser that emits light at 1064 nm. This wavelength is in the near infrared region of the electromagnetic spectrum and thus directly heats tissue. It is this heating effect that causes tissue coagulation and causes bleeding to cease. An advantage of this wavelength as compared, for example, with the argon laser (emitting mainly at 488 nm and 514.5 nm) is the fact that argon laser radiation is more readily absorbed by blood than is Nd-YAG laser radiation. Thus, the Nd-YAG beam can penetrate the blood coming from a bleeding lesion and photocoagulate the bleeding vessel, whereas the argon laser beam is more highly attenuated via photon absorption by blood. In addition to the factor of beam attenuation by absorption, there are fundamental differences between the Nd-YAG and the argon laser in the mechanism by which heat is generated in tissue to coagulate the bleeding vessel. The Nd-YAG beam as noted above, is infrared in its energy locus and thus heats the photon-absorbing tissues directly. The argon beam is in the visible spectrum and its mechanism of tissue heating is more complex, involving the absorber-mediated transition of electronic energy into the lower energy, vibrationally induced infrared spectrum.

Fruhmorgen and associates first reported the use of the argon laser for therapy of UGI bleeding in man in 1976 (1). Dwyer and associates reported on its use for photocoagulation in the canine stomach in 1975 (2). Kiefhaber and associates reported in 1977 on the use of the Nd-YAG laser to photocoagulate bleeding ulcers (3).

The factors that determine the effect of the laser on tissue include: wavelength, tissue constituents (absorption and scattering), beam diameter at the focal point in tissue, pulse duration, and laser power setting. All of these factors will play a role in determining the temperature reached at the focal point of the photon beam in tissue.

RATIONALE

The fundamental rationale for the use of laser photocoagulation is to resolve UGI bleeding without resorting to surgery. The idea is that the mortality rate for emergency surgical intervention in acutely bleeding patients is high, and it is postulated that endoscopic methods will result in a decreased incidence of mortality.

In any evaluation of methods utilized to stop upper gastrointestinal bleeding, a primary consideration is the determination of the percentage of patients that will stop bleeding with no therapeutic intervention whatsoever. A study on this topic prospectively analyzed 175 patients with UGI bleeding during a 12-month period (4). The author found that in approximately 80 percent of these cases the bleeding was self-limited. The greatest percentage of cases were due to varices and duodenal ulcers, but hemorrhagic gastritis, gastric erosion, esophagitis, Mallory-Weiss syndrome, and gastric cancer were also represented. The figure of approximately 80 percent of UGI bleeding episodes being self-limited is roughly consistent with other published studies (5,6). The clear implication of these studies is that in approximately 80 percent of cases of UGI bleeding, no major therapeutic intervention is required in order to achieve cessation of hemorrhage. Therefore, studies on the effectiveness of any therapeutic modality

designed to stop UGI bleeding should evaluate the 20 percent of patients who do not stop bleeding spontaneously. The prospective identification of this group of patients is a crucial but difficult matter. There are some conditions that suggest but do not unequivocally identify in a prospective manner members of this group. Upper gastrointestinal bleeding that begins more than 24 hours after hospital admission has an approximately 2.5-fold greater probability of persistence than UGI bleeding that presents as the initial complaint (4). Rebleeding during hospitalization, arterial pumping seen at endoscopy, or bleeding requiring three or more units of blood in 24 hours are also suggestive. Another positive prognosticator for unremitting UGI bleeding is seen at endoscopy and is known as the visible vessel (7,8), or the sentinal clot (9-11). Griffiths and associates performed endoscopy on 317 patients with UGI bleeding, and in 28 of these a "visible" vessel was seen in the ulcer. All of these patients eventually came to surgery because of recurrent or uncontrolled hemorrhage, whereas only 40 of the 317 patients without a visible vessel required surgery. In addition, when patients with a visible vessel were treated medically instead of surgically, the mortality rate was 83 percent as compared with 9 percent in patients without a visible vessel. The authors noted that the usual criterion for surgery is the existence of continuous or recurrent hemorrhage, and that patients with visible vessels fulfilled this criterion (7). In the study of Storey and associates, 19 of 34 patients with visible vessels (56%) had rebleeding, whereas 1 of 13 patients (8%) with other stigmata of recent hemorrhage (but no visible vessel) had rebleeding (8). The authors concluded that in patients with UGI bleeding, "rebleeding occurs almost exclusively" in ulcers with visible vessels, but only half the ulcers with visible vessels undergo rebleeding. Others (9-11), have presented evidence that the entity seen at endoscopy is not a visible vessel but, rather, is a thrombosis extending from a tear in the side of an artery lying in the ulcer base and have termed it a "sentinal clot" (11).

The reason for the tremendous interest in laser photocoagulation is the relatively high mortality that occurs when the traditional surgical approach is used to treat bleeding in high-risk individuals under emergency conditions. Thus, the appropriate experimental evaluation for the effectiveness of laser photocoagulation and other nonsurgical approaches to UGI bleeding is to compare the coagulation effectiveness, mortality, and morbidity of these alternatives with the coagulation effectiveness, mortality, and morbidity of traditional surgery on the approximately 20 percent of UGI bleeders who do not cease bleeding with medical therapy alone. Dronfield and associates evaluated the mortality rates in patients with bleeding peptic ulcers who were randomly admitted on a "rota" basis to two hospitals (12). Bleeding seemed equally severe in both groups but one hospital had a more aggressive surgical policy than the other with regard to bleeding peptic ulcers. A patient with a bleeding ulcer who was admitted to the more conservative institution had a 32 percent chance of being operated on as compared with 48 percent at the other hospital. At the more conservative hospital, 6 percent of patients died nonoperatively as compared with 9 percent in the more aggressive program. In another study, Foster and associates examined the factors influencing the mortality following operations for UGI hemorrhage (13). They found a postoperative mortality of 62.9 percent in patients where massive UGI bleeding began while hospitalized for other illness. The presence of associated major system disease (renal, pulmonary, hepatic, and cerebrovascular) correlated with an increased mortality rate. In another study, Welch and Burke evaluated 1,020 patients with gastric ulcer admitted to hospitals over a 10-year period (14). They found a mortality rate for emergency surgery of approximately 25 percent as compared with 2.4 percent for elective surgery. In general, it would appear that if nonsurgical methods can result in decreased mortality in this group of patients with unremitting or recurrent bleeding, then these methods constitute important therapeutic modalities.

REVIEW OF THE LITERATURE

Joffe utilized the Nd-YAG laser on 19 patients who fulfilled the study criteria of presence of shock or supine hypotension as a result of blood loss, an initial hemoglobin of less than 10 gm/dL, and a transfusion requirement of over 3 pints of blood (15). Initially, photocoagulation stopped the bleeding in 17 patients (89 percent). The two patients who continued to bleed underwent surgery but died. Rebleeding occurred in five patients, with repeated laser photocoagulation unsuccessful in two. No instances of perforation occurred. The author noted that the patients in this study would usually be considered for emergency surgery. It was not indicated whether any of the patients were bleeding from esophageal varices.

Homer and associates performed a trial of YAG laser photocoagulation on 42 patients with stigmata of recent hemorrhage (16). Seventeen were treated with the laser and 25 were managed conservatively. The only lesions considered were single duodenal or gastric ulcers. Stigmata of recent hemorrhage were defined as a visible vessel whether actively bleeding or not, a diffuse area of oozing at the base of an ulcer but no visible vessel, or a small clot in an ulcer crater that could not be washed away. Following endoscopy, all patients were treated with cimetidine, and all further clinical decisions were made by a physician unaware of whether the patient was in the laser group or control group. There was no significant difference in the number of patients who rebled and required surgery, mortality rate, length of stay in hospital, or amount of blood transfusion required in either group. The authors had one instance of laser therapy precipitating massive bleeding from an oozing artery in the base of a duodenal ulcer. They concluded that the routine use of the YAG laser for bleeding peptic ulcers in a district general hospital is not justified.

Swain and associates performed a controlled trial of YAG-laser photocoagulation on 138 patients (70 in the treatment group and 68 in the control group) with ulcers and stigmata of recent hemorrhage (SRH) as seen during endoscopy (17). The SRH included a visible vessel, oozing, a fresh or altered blood clot adhering to the ulcer, or black spots seen in the crater (8). Patients were placed in three groups: those with a visible vessel, those with other SRH, and those with a clot that could not be washed off before therapy. In the group as a whole, 7/70 laser-treated and 27/68 control patients rebled. In the visible vessel group, 6/39 laser-treated patients rebled as did 23/43 control patients. In the other SRH group, 0/17 laser-treated patients rebled and 1/13 control patients. In the "overlying clot" group, 1/13 laser-treated patients rebled as did 2/11 control patients; 7/70 laser-treated patients required emergency surgery, as compared with 24/68 control patients. One laser-treated patient died as compared with 8 controls. The authors precisely described their technique as follows: The fiber tip was positioned approximately 1 cm from the target, and "fired in pulses of 0.5 seconds (80W), the aim being to deliver 8 to 10 pulses in a tight ring of contiguous spots around the bleeding point to coagulate the bleeding vessel distally and proximally." In active bleeding, higher laser power settings were sometimes utilized. No perforations occurred as a result of laser therapy. Four patients with a nonbleeding visible vessel bled on treatment. All stopped bleeding with further laser pulses but one rebled later. The authors commented that "the results of this trial suggest that the Nd-YAG laser significantly reduced the rebleeding rate, the need for emergency surgery, and consequently mortality." In the study of Homer and associates (16), it is not clear that the same technique was used as in that of Swain and associates (17). In the Swain study, the laser pulses were delivered "... in a tight ring of contiguous spots around the bleeding point to coagulate the bleeding vessel distally and proximally. Higher powers were sometimes used in the presence of active bleeding." In the study of Homer, the laser "was fired until the target area was charred indicating photocoagulation (usually 7-8 pulses, maximum 17). "It is not

demonstrated that charring correlates with profound coagulation of the bleeding vessel. McLeod and associates conducted a single blind controlled study on the use of the YAG laser for photocoagulation of single vessel bleeding from peptic ulcers (18). Over a 20-month period, 184 patients were endoscopically determined to be bleeding from a single vessel source in a peptic ulcer. Patients were candidates for the protocol if they had GI bleeding during the previous 24 hours and had active arterial bleeding seen at endoscopy or at least one of the following criteria was fulfilled: (1) presence of shock on or after admission as a result of blood loss; (2) an initial or subsequent hemoglobin determination of below 10 gm/dL; or (3) the requirement of a blood transfusion in the preceding 24-hour time period. In addition to the above clinical trial entry criteria, one of the following endoscopic criteria also had to be satisfied; (1) presence of a gastric or duodenal ulcer thought to be the source of the bleeding with either an artery or a red, blue, or black spot in the ulcer base; or (2) presence of a solitary vessel, bleeding or nonbleeding, thought to be the source of the hemorrhage. Of the 184 patients bleeding from peptic ulcers having single vessels, 130 failed the study entry criteria but ceased bleeding with conservative therapy. Forty-five patients met the study entry criteria: Of these, 25 were bleeding from ulcers with spots. The bleeding in these patients stopped irrespective of the treatment modality. Twenty patients had arterial bleeding; eight were randomized to placebo treatment and eight had YAG laser therapy. Four other patients were allocated to laser therapy but did not receive it for various reasons. Of the eight patients with arterial bleeding who had placebo treatment, all required emergency surgery. Of the 8 patients who received laser therapy, only one required surgery. The authors concluded that "laser treatment reduces the incidence of further hemorrhage and the need for emergency surgery, but the technique is difficult and not always applicable."

Rohde and associates reported in an abstract on a prospective trial of YAG laser therapy on 105 patients with active UGI bleeding plus melena and/or hematemesis (19). There were 62 treated patients and 43 controls. It is difficult to evaluate this study because the authors expressed mortality without indicating whether they meant number or percentage. If number was meant, then 24/62 (39%) laser-treated patients died and 27/43 (63%) control patients died. If percentage was meant, then 24 percent died in the laser treated group and 27% in the control group. The authors commented that their results "suggest doubt concerning the value of endoscopic laser therapy." The types of lesions treated (or the presence of bleeding from esophageal varices) were not indicated, nor was the technique presented.

Krejs and associates conducted a controlled randomized trial of YAG laser photocoagulation for acute peptic ulcer bleeding on 174 patients with active bleeding or stigmata of recent hemorrhage due to peptic ulcer (20). Eighty-five patients were treated with the YAG laser and 89 patients were in the control group. Patients and their physicians were unaware of whether the laser had been used. The investigators summarized their findings as follows:

> There was no significant difference in a number of outcomes between the group treated with laser photocoagulation and the control group. Continued bleeding or rebleeding was observed in 22 percent of the laser-treated group and in 20 percent of the control group. Urgent surgery was necessary in 16 percent of the laser-treated patients and in 17 percent of the controls. Laser-treated patients spent a mean of 41 hours in the intensive care unit, and controls spent a mean of 32 hours. The mean hospital stay was 12 days in the laser treated group and 11 days in the control group. When patients with active bleeding were analyzed repeatedly, there was no significant difference in outcomes, even though laser photocoagulation stopped active bleeding in 88 percent of cases. Among patients with visible vessels, rebleeding occurred in 5 of 14 (36 percent) who received laser treatment and 2 of 15 (13 percent) who did not. Laser treatment precipitated bleeding in four patients and duodenal verification in one (20).

The authors concluded that "Nd:YAG-laser photocoagulation does not benefit patients with acute upper gastrointestinal bleeding from peptic ulcers." It is noteworthy that 221 patients were excluded from the study because they were too medically unstable to be moved from the intensive care unit or emergency room to the laser location. A consultant to OHTA noted that these seriously ill patients not included in the study were the ones most apt to benefit from the therapy, and in whom you would want, to the greatest extent, to avoid surgery. The lack of portability of the therapeutic Nd-YAG laser is an important disadvantage of the technique.

Trudeau and associates conducted a study on YAG laser photocoagulation of bleeding ulcers with visible vessels (21). Thirty-three patients had visible vessels with stigmata of bleeding ("fresh bleeding or altered blood clot adherent to the lesions"). Eighteen patients were treated with the laser and 15 served as controls. All patients received cimetidine, antacids, and nasogastric suction. Initial control was obtained in 100% of the laser-treated group and 53% of the nonlaser group. Rebleeding for laser-treated patients was 11 percent versus 40 percent for the nonlaser-treated group. Mortality was 11 percent (laser-treated) and 33 percent (nonlaser-treated). Approximately 27 percent of nonlaser-treated patients required surgical treatment, whereas only 5.5 percent of the laser-treated group needed surgery.

The authors concluded that "in patients with endoscopic stigmata of bleeding with visible vessels, Nd-YAG laser photocoagulation is highly successful in bleeding ulcer control, reduces the number of rebleeds, improves survival, and reduces the need for urgent surgery when compared to a similar group of patients receiving standard medical therapy." No discussion or details of technique were presented.

Rutgeerts and associates conducted a trial of YAG laser photocoagulation on 152 patients with UGI bleeding due to stomach ulcers or erosions, duodenal ulcers or erosions, Mallory-Weiss tears, esophageal ulcers, and stomach carcinoma (22). No esophageal or fundal varices, or diffuse hemorrhagic lesions of the stomach or esophagus were

included. Patients were divided into three groups. Group 1 consisted of 23 patients with spurting arterial bleeding. The human experimentation committee disallowed the randomization of these patients and all were treated by laser. Group 2 consisted of 86 patients with active bleeding in whom arterial spurting was not seen. Group 3 consisted of 43 patients who were not bleeding at endoscopy but did have stigmata of recent hemorrhage consisting of "a red clot or a visible vessel at the base of the ulcer." The patients of Groups 2 and 3 were randomized into laser treatment subgroups and controls (within each group). In the patients of Group 1, spurting arterial bleeding was stopped in 87 percent with laser therapy, but the recurrence rate was 55 percent. Sixty-one percent of the 24 patients had to be operated on. The overall mortality for the entire group was 7/23 (30%). The authors noted that the operative rate of 61 percent was lower than the previous operative rate for patients with arterial spurting (96%). In group 2, 70 actively bleeding lesions were treated in 46 patients. The control group consisted of 40 patients with 60 lesions. One hundred percent of the laser treated patients stopped bleeding whereas 77 percent of the control patients stopped. Bleeding recurred in 3/46 (7%) of the laser patients as compared with 6/31 (20%) of the control patients. One laser patient went to surgery (2%) as compared with 5 control patients (13%). In terms of mortality, however, six laser patients died (13%) as compared with six control patients (15%). In Group 3, bleeding recurred in 18 percent of the laser treated patients and in 31 percent of the control patients. Twelve percent of the laser patients went to surgery as compared with 23 percent of the control patients. In overall mortality, 12 percent of the laser patients died, as did 15 percent of the control patients. None of the differences in Group 3 were statistically significant. Overall, the authors indicated that mortality rates were not influenced by YAG laser therapy in any of the groups, but that the technique effectively stops bleeding in 87-100 percent of patients, tends to prevent

bleeding, and lowers the operative rate in patients with spurting arterial hemorrhage. The text of this study makes it evident that many of the deaths were due to causes other than gastrointestinal bleeding.

Ihre and associates conducted a controlled randomized study on the use of YAG laser in massive UGI bleeding (23). Of 66 patients belonging to the laser Group, 23 were bleeding at endoscopy. Fifteen of these were treated with the YAG laser and coagulation was achieved in 14. Seven of these 14 rebled, resulting in surgery in 5. One of the five died postoperatively. Two patients expired from bleeding esophageal varices and hepatic failure. In the other 43 patients in the laser group not bleeding at endoscopy, nine patients had rebleeding, with surgery required in three. One died postoperatively. Four other patients from this group died; three from bleeding esophageal varices with hepatic failure, and one from bleeding of unknown etiology. Sixty-nine patients comprised the control group. In 19 (of the 69), bleeding lesions were found at endoscopy, and in 50 (of the 69), no bleeding was found. In the 19 bleeding patients, five required surgery and two died postoperatively. Three additional patients died of esophageal varices and hepatic failure. In the 50 nonbleeding control patients, 8 later had recurrence of bleeding. Four had esophageal varices and two died. In summary, 9 patients (5 with esophageal varices) died in the laser group (66 patients), and 7 patients (5 with esophageal varices) died in the control group (69 patients). The authors noted that there were no statistically significant differences between the laser group and the control group with regard to mortality, transfusion requirements, or duration of stay in hospital. However, they further noted that the sample was too small to make any definitive conclusions, but that "no great advantages are to be expected with the laser treatment as compared to an aggressive diagnostic and surgical attitude" (23). The precise details of the photocoagulation technique were not presented.

Rutgeerts and associates used the YAG laser on 130 patients with UGI bleeding, including cases with arterial spurting and stigmata of recent hemorrhage (fresh red clot

or nonbleeding visible vessel) (24). Lesions with old stigmata of bleeding were not treated. Esophageal varices were not included. Initial hemostasis was achieved in 95 percent of patients but rebleeding occurred in 22 percent. Fifteen percent of patients had to be operated on and 17 percent of the patients died. In 8 percent, death was directly related to bleeding, whereas in the other 8 percent death was due to underlying disease. In 36 patients with ulcers containing visible vessels, 27 were spurting at endoscopy and 9 were not bleeding. Initial control of bleeding was achieved in 83 percent of these patients but bleeding occurred in their series. In 20 percent of patients, initial laser pulses increased the bleeding rate or induced arterial bleeding. This "could mostly be controlled by continued treatment" (24). "Photocoagulation around the vessel before hitting the vessel itself would decrease this risk" (24). In addition, it was suggested that the frequency of bronchopulmonary complications arising during emergency endoscopy is underestimated and that when aspiration of blood is inspected, immediate bronchial cleaning has to be instituted. The authors pointed out that in patients with visible vessels, only 50 percent avoided surgery; in other words, hemostasis was achieved in 50 percent. However, in the time before the laser was available in their hospital, 87 percent of patients with arterial spurting required surgical intervention.

Fleischer conducted a controlled trial of YAG laser therapy for active esophageal variceal bleeding (21). The laser treatment group had 10 patients as did the control group. Initial cessation of bleeding was achieved in seven laser-treated patients but in none of the control group patients. Four of the seven who were initially controlled with the laser had rebleeding 12-48 hours later. Therefore, 3 of 10 laser-treated patients had relatively permanent cessation of bleedings. Both groups had similar transfusion requirements. Six of the ten laser group patients survived and 4 died. Three patients in the control group recovered and 7 died. No perforations occurred, and in two patients the laser treatment increased bleeding. In one of these the increased bleeding was controlled with further laser treatment at the initial session. No prohibition was made

for retreatment of rebleeding, because the Institutional Study Design Advisory Committee felt that the patient should receive more traditional therapy if the experimental laser treatment failed. The author concluded as follows:

> Endoscopic Nd-YAG laser therapy effectively provides initial hemostasis in many patients with severe, persistent bleeding from esophageal varices. There is, however, a high rate of rebleeding so that laser therapy does not provide definite treatment. If this point is appreciated, the laser can be applied as an interim solution to buy time to stabilize the patient so that a more definitive plan can be instituted (25).

Bown and associates conducted a study on the use of the argon and YAG lasers in the treatment of vascular anomalies of the upper gastrointestinal tract (26). From 1979 to 1981, only the argon laser was available at the hospital where the study was conducted. In 1981, a YAG laser became available and this was used on all subsequent cases. "A positive diagnosis was based on the identification of one or more bright red lesions on the mucosa (occasionally associated with small areas of superficial ulceration). These were raised (umbilicated), flat, or depressed, but all lesions in any one patient were similar. Lesions seen to bleed spontaneously or which oozed on gentle washing or on treatment were thought most likely to be the site of significant blood loss" (26). The size ranged from 1 cm to less than 1mm in diameters. The authors noted that deep cavernous lesions are sometimes seen but are not suitable for laser photocoagulation. Patients with UGI lesions as described, typical mucocutaneous lesions, and a positive family history were classified as having hemorrhagic telangiectasia. Patients with UGI lesions as described but without mucocutaneous lesions or a positive family history were classified as having angiodysplasia. In all cases of hemorrhagic telangiectasia, there were too many lesions to treat at one time, and therefore the laser photocoagulation was repeated every 4 days. Eighteen patients were treated; eight with hereditary hemorrhagic telangiectasia and 10 with angiodysplasia (both single and multiple). The results were as follows: Four patients with hereditary hemorrhagic telangiectasia, five with solitary angiodysplasias and three with multiple angiodysplasias

had their transfusion requirements lowered to "minimal" levels. Two of these patients required no transfusion at all for a period of 2 years (in the previous 2-year period, one of these patients required 129 units of blood and the other 52 units of blood). Four patients (of the 18) went to surgery. Two of these were not controlled by laser photocoagulation, and in the other two, the laser was not available at the time the paper was written but were noted to have shown reductions in transfusion requirements. The authors noted that both the argon and YAG laser were effective, but the YAG appeared to have more lasting results. They suggested that the YAG could penetrate to the main areas of vascular ectasia in the submucosa and that this might account for the better results, although the YAG was considered to have a higher risk than argon of causing bleeding in the first days after surgery.

Goff conducted a randomized trial of the Nd-YAG laser versus bipolar electrocoagulation on 19 patients with solitary nonvariceal sources of upper gastrointestinal bleeding (27). Eight received the laser and 11 had bipolar electrocoagulation. In the laser group 37.5 percent had no bleeding after treatment, and 54.5 percent of the bipolar group had no bleeding after treatment. This difference was not statistically significant at the 0.1 level, and the authors concluded that the YAG laser and bipolar electrocoagulation are equally effective for the treatment of solitary bleeding UGI lesions. Further, the author indicated that due to its relatively low cost and care of transplantation, the bipolar unit may be the method of choice for causing cessation of bleeding UGI lesions until a better method is developed.

Johnston and associates have conducted an extremely interesting comparative study on the hemostatic effectiveness of the YAG laser and the heater probe on the endoscopic treatment of major bleeding from peptic ulcers (28). "YAG laser treatment routinely involved application of laser pulses circumferentially around the bleeding point. If circumferential pulses did not produce hemostasis, infrequent pulses were delivered directly to the bleeding site." Both the YAG and the heater probe groups were

described as demonstrating features of major hemorrhage that would ordinarily require surgical intervention. Ultimate hemostatic success (lack of further bleeding during the hospitalization) was realized in 69 percent (24/35) of YAG-treated patients, as compared with 95 percent (19/20) heater probe patients. Initial therapy was less successful with the YAG (80%) than with the heater probe (100 percent). "Rebleeding 1-6 days after successful initial therapy was somewhat higher with heater probe (30 percent) than YAG (21 percent); of the six cases of rebleeding after heater probe four had been treated initially for active arterial bleeding, whereas rebleeding with YAG primarily occurred after treatment of a nonbleeding sentinal clot (5/6 cases)." The authors felt that the heater probe was faster, more convenient and safer to use than the YAG laser.

Rutgeerts and associates performed a randomized trial comparing BICAP electrocoagulation with YAG-laser photocoagulation in patients with peptic ulcers and a high probability for persistent or recurrent bleeding (29). Fifty patients were enrolled in each treatment group. All lesions were pretreated with 1 percent epinephrine. Permanent hemostasis was obtained in 72 percent of both groups with one treatment. Two treatments generated cumulative permanent hemostasis of 88 percent in the laser group and 86 percent in the BICAP group. One perforation occurred in each treatment group. The authors concluded that both therapeutic methods were "highly and equally effective in the treatment of severe bleeding from peptic ulcers."

Overholt has described with great precision his technique and general approach to endoscopic laser photocoagulation for UGI bleeding (30,31).

> The gastroenterologist using lasers in the treatment of a massive UGI hemorrhage should have a surgeon immediately available. The endoscopist should be prepared to spend 1 1/2 - 3 hours or more for active bleeding cases, requiring considerable scheduling flexibility. Treatment of visible vessels or spots may require less time, but to "sandwich" a laser case into a busy schedule without allowing adequate time is to invite disaster. Indications and contraindications for laser photocoagulation generally follow those of endoscopy in patients with UGI hemorrhage. If endoscopy is indicated and feasible, laser therapy can be considered. In most situations for patients with torrential bleeding which cannot be cleared adequately for visualization, emergency surgery is indicated. With lesser degrees of bleeding, attempts at

laser therapy are possible. These patients with SRH including active bleeding, a visible vessel or a fresh clot are ideal candidates for laser photocoagulation. As discussed later, the visible gastroduodenal artery should be approached with great caution if at all. The greatest contraindication is any one or a combination of (1) the untrained endoscopist, (2) the unprepared assistant, or (3) the inadequate facility.

It was suggested that a visible vessel should be rimmed with shots of laser energy at about 2-3 mm from the vessel. This should be completed within 2-3 minutes because heat from the photocoagulation will rapidly cause edema, which will impair visualization of the radiation field. It was noted that bleeding often occurs during laser photocoagulation, and the heat-generated edema resulting from rimming the vessel with laser energy, may compress the vessel and thereby offer some protection against massive hemorrhage. It was suggested that for small arteries or visible vessels, direct exposure of the vessel to the laser beam could be considered only after the circumferential application of laser energy had been completed. If active bleeding is precipitated by the procedure, the endoscopist has only a short time (in the range of minutes) to effectuate further phototherapy, because blood will rapidly obliterate the field of view. A surgeon should be available and be called if torrential bleeding occurs. Overholt particularly emphasized attention to the gastroduodenal artery. In general, that author considered the massively bleeding gastroduodenal artery to be not treatable by endoscopic therapy, whereas an oozing or quiescent gastroduodenal artery may be suitable for a therapeutic endoscopic approach. It was emphasized however, that any interaction with the gastroduodenal artery must be undertaken with extreme care, and then only for chronically ill, poor surgical risk patients with documented continued bleeding or good surgical risk patients with documented recurrent bleeding.

DISCUSSION

The National Institutes of Health (NIH) has advised the Office of Health Technology Assessment (OHTA) that both argon and YAG lasers have been widely used

endoscopically to photocoagulate bleeding from the upper gastrointestinal tract, and while there is a considerable body of literature on these technologies that suggest they are effective therapeutically, the results of controlled clinical trials have been contradictory and/or lacking in statistical power to resolve the question of efficacy for treating the variety of lesions to which they have been applied. In this context the NIH wished to take particular note of the latest controlled randomized clinical trial, conducted by Krejs and associates, which concluded that Nd:YAG laser photocoagulation does not benefit patients with UGI bleeding from peptic ulcers (20). This study is discussed on page 8. The NIH further advised OHTA that endoscopic laser photocoagulation appears to be a reasonably safe procedure for controlling UGI bleeding, but that the main disadvantages with the technology are that the lasers are expensive and are not portable or suitable for use at the bedside. Other, less expensive and more improved portable technologies are desirable, and appropriate controlled clinical trials to determine the efficacy and safety of these newer technologies in the management of UGI bleeding should be done. In this context the NIH wished to take particular note of the latest prospective controlled trial of multipolar electrocoagulation in the treatment of UGI bleeding by Laine, who concluded that multipolar electrocoagulation markedly improves the hospital course in patients with major non-variceal UGI bleeding (32).

The Food and Drug Administration (FDA) has advised OHTA that the argon laser was a preamendment device and was classified as Class II by the General Medical Devices Panel. Such devices are reviewed under 510(K) for which no Summary of Safety and Effectiveness is needed. In 1982, the Nd-YAG laser was determined to be substantially equivalent to the argon laser. Such equivalence was established via clinical studies conducted by each of the laser manufacturers under an Investigational Device Exemption for a number of indications including endoscopic hemostasis.

The American Society for Gastrointestinal Endoscopy has advised OHTA that:

1. Of the lasers in use for the treatment of UGI bleeding in the United States, Europe, and Japan, over 95 percent are Nd-YAG lasers.
2. Endoscopic laser therapy has been used for both variceal and non-variceal UGI bleeding.
3. For variceal bleeding it is not used as frequently as injection sclerotherapy, and concern exists that laser therapy may not as effectively obliterate the vein as injection sclerotherapy and, therefore, may not be of long-term benefit.
4. For nonvariceal bleeding, the laser has been most often used for discrete lesions such as gastric ulcer or duodenal ulcer, Mallory-Weiss tears, or vascular anomalies. It is less commonly applied to diffuse lesions such as hemorrhagic gastritis.
5. Data is available from over 300 centers in the United states and over 200 in Europe and Japan regarding the efficacy of laser photocoagulation for UGI bleeding in uncontrolled series. Initial hemostasis can be expected in over 80 percent of cases but an incidence of rebleeding from 5-40 percent has been reported.
6. Data about the efficacy of laser therapy for bleeding peptic ulcers are available from 11 controlled trials but it should be stressed that many of these studies involve a relatively small number of patients, and therefore, statistical significance may be difficult to demonstrate.
7. Of the three controlled argon laser studies, one concluded that the laser was not influential in affecting outcome whereas the other two smaller studies demonstrated that the laser improved both initial hemostasis and outcome.

8. Of the eight controlled studies with the YAG laser, four did not demonstrate benefit and four did demonstrate benefit.
9. There is more data from controlled studies demonstrating that the laser is of benefit in UGI bleeding than with any other modality.
10. Endoscopic laser therapy has been effective for treatment of Mallory-Weiss tears and vascular anomalies. No information exists from controlled randomized studies.
11. Endoscopic laser therapy for the treatment of upper gastrointestinal bleeding has proven to be very safe. Not a single perforation has been reported from any controlled study. In noncontrolled studies, the incidence of perforation is reported in the range of 1-2 percent. This is an encouraging figure in view of the critically ill nature of the large majority of these patients. Laser-induced bleeding is a more common occurrence, ranging from 2-10 percent.

The American Society for Gastrointestinal Endoscopy considers laser photocoagulation to be a safe, effective, modern clinically accepted therapeutic modality and not an investigational technique. The patient population most likely to benefit are those with discrete bleeding lesions such as ulcers, Mallory-Weiss tears, and vascular anomalies. It is unknown at present how the laser compares in regard to safety and clinical efficacy with other endoscopic modalities.

The American Digestive Disease Society has advised OHTA that laser therapy presents an excellent, safe way for physicians to deal with problems that can be treated with laser techniques. However, not every gastroenterologist sees laser therapy as a panacea, and the cost factors and lack of portability often indicate that other accepted modalities can provide excellent alternatives. It was indicated that in the main, however, laser techniques are fast becoming a major approach to UGI treatment.

The American Medical Association sent OHTA its Diagnostic and Therapeutic Technology Assessment (DATTA) report on endoscopic management of gastrointestinal tract hemorrhage (33). The question of the safety and effectiveness of laser photocoagulation (argon or YAG) for the treatment of bleeding in the esophagus and stomach-duodenum was submitted to 50 DATTA panelists. For the stomach-duodenum, 56 percent of the panelists considered it established therapy, 36 percent of the panelists considered it investigational, and 8 percent were undecided. For the esophagus, 39 percent of the panelists considered laser photocoagulation to be established therapy, 47 percent considered it investigational, 11 percent were undetermined, and 3 percent considered it unacceptable. It was noted that for the argon laser, 90 percent of the beam is absorbed at a tissue depth of 1 mm, whereas for the YAG laser, 90 percent of the beam is not absorbed until a tissue depth of 4 mm. This increased depth of beam penetration in combination with the comparatively minor absorption of the YAG beam by blood, may make the YAG more appropriate for the photocoagulation of bleeding vessels. The DATTA report emphasized that not all bleeding lesions can be reached with the laser and that there are apparently no controlled studies comparing the laser with other therapeutic modalities for UGI bleeding such as electrocoagulation. "

> Despite the rapid growth of laser technology and the endoscopic use of lasers, many DATTA panelists mention several adverse features: cost ($100,000), immobility, extensive training required, and lack of evidence of superiority over existing technologies. Panelists also noted the need to add a filter to the eyepiece of the endoscope to prevent retinal damage by backscatter of the laser beam. Even the most ardent advocates indicated that laser therapy is not appropriate for all patients. The most appropriate candidates would be those patients with massive bleeding that would not cease spontaneously and who may be at high risk because of cardiac or other major preexisting disease

A number of gastroenterologists have written to OHTA to indicate support for the use of the YAG laser in UGI bleeding.

The primary complications arising from endoscopic laser photocoagulation include perforation and the indication of massive bleeding (30,31,34,35,36,37). Fleischer has noted that in the eight controlled trials with the YAG laser and the three controlled trials with the argon laser (for the treatment of acute nonvariceal bleeding), not one instance of perforation was reported. Kiefhaber reported on 837 successfully treated bleeding episodes in 667 patients (35). These included 155 esophageal and gastric varices, 96 Mallory-Weiss tears, 491 ulcers (including ulcerated carcinomas), 81 multiple erosions and "Osler hemangiomas," and 41 episodes in the colon and rectum. In the bleeding acute ulcers treated, 9 perforations occurred. The reasons given included too high-power density in the treated locus, and photocoagulations on the same spot in more than two sessions. Thus the perforation rate for bleeding ulcer was 9/491 x 100 = 1.8 percent. However, the author noted that 13 perforations occurred in lesions that were not laser treated. The reviews of Fleischer and Overholt, both indicate an incidence of perforation of 1-2 percent in uncontrolled studies (31,37). It has been suggested that "as the endoscopist becomes more experienced in the use of laser, it would seem that perforation will occur infrequently" (31).

The evidence suggests that the use of laser photocoagulation requires experience, proper training, and a judicious, temperate, relatively conservative approach. There is little doubt that elevation of laser power and/or repeated pulse applications to the same tissue locus can result in perforation. Judgement, training, and experience are required in order to determine how much is enough and when to stop.

If the controlled studies on laser photocoagulation for non-variceal UGI bleeding are considered, it is somewhat perplexing that some of these studies yield significant positive results for laser therapy and some do not. Why should this be? For one thing, it is possible that not all investigators used the same technique. Thus, standardization of technique from those investigators with the best results might yield more uniform conclusions in the future. Additionally, one must take into account the extent of illness

in these patients from other underlying diseases. If patients in one study were sicker than patients in another study, then the sicker patients might have a higher mortality rate. As previously noted, the NIH commented that a number of the controlled clinical trials have been lacking in statistical power to resolve the question of efficacy of laser photocoagulation for the treatment of UGI bleeding. In this context, two publications are of interest and potential relevance. Freiman and associates reexamined 71 "negative" randomized controlled trials to determine if the investigators had studied a large enough sample to give a high probability of detecting a 25 percent or 50 percent therapeutic improvement (38). Sixty-seven of the trials had a greater than 10 percent risk of missing a 25 percent therapeutic improvement, and 50 of the trials could have missed a 50 percent improvement. The authors indicated a concern for the probability of missing a therapeutic improvement because of small sample size. Bourne has also commented interestingly on the importance of using a sample size sufficient to detect with reasonable power a real difference that is clinically important (39). The potential relevance, if any, of these statistical concepts to the controlled trials on laser photocoagulation is a topic for further analysis. It is also possible that the negative studies are in fact correct in their conclusion.

As noted previously, approximately 80 percent of patients with UGI bleeding will stop bleeding with no therapeutic intervention whatsoever. Thus the proper group of patients for the analysis of any technique for the treatment of UGI bleeding, is the 20 percent of patients who do not cease bleeding spontaneously. As noted in the Rationale section, the patients who do not cease bleeding spontaneously and, therefore, require emergency surgery have a relatively high mortality rate. If any of the thermal techniques such as laser photocoagulation can lower the mortality rate in this group of

patients by avoiding the necessity of surgery, then the thermal technique is of positive benefit. A number of authors of various laser photocoagulation studies have noted that the patients who had cessation of bleeding as a result of laser therapy would have otherwise been candidates for and required surgery in order to stop the bleeding.

SUMMARY

Endoscopic laser photocoagulation is a technique for the treatment of upper gastrointestinal bleeding, whereby the laser energy is used to create tissue heating so as to seal the bleeding vessel. The rationale for its use lies in the relatively high mortality rate which occurs for bleeding patients who require emergency surgery to yield cessation of bleeding. A number of controlled studies have been performed. Some of these studies demonstrate positive results and some do not. It is notable that some of the positive studies indicate that a number of the YAG laser treated patients would have otherwise been candidates for emergency surgery. NIH has advised OHTA that endoscopic laser photocoagulation appears to be a reasonably safe procedure for controlling UGI bleeding, but while there is a considerable body of literature suggesting that the technique is therapeutically effective, the results of controlled clinical trials have been contradictory and/or lacking in statistical power to resolve the question of efficacy. The majority of consultants for the AMA DATTA report indicated laser photocoagulation to be an established therapy for bleeding in the stomach and duodenum. The American Society for Gastrointestinal endoscopy has advised the OHTA that they consider endoscopic laser photocoagulation to be a safe, effective, clinically accepted therapeutic modality, and not an investigational technique. Most of the controlled studies have reported no instances of perforation, but the uncontrolled studies report perforation incidence of 1-2 percent. It is obvious that training, experience, and good judgment are required in order to determine when to stop laser therapy and how much is enough. Instances of

perforation, of rebleeding after laser photocoagulation, and of laser-induced bleeding are major sources of concern. In view of the contradictory results in controlled studies, it would be appropriate to reevaluate this topic in approximately 2 years.

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Endoscopic laser photocoagulation for the treatment of upper gastrointestinal bleeding involves the application of laser light to a bleeding lesion through an optical fiber that passes to the gut via a channel of a flexible endoscope. The Nd:YAG laser emitting at 1064 nm is most frequently used. It is difficult to arrive at definitive conclusions on this topic because approximately 80 percent of patients with upper gastrointestinal hemorrhage cease bleeding spontaneously. The results of controlled trials have been mixed. Some demonstrate benefit with the laser and some do not. At present, a drawback to the use of the laser is its lack of portability. Laser-induced bleeding remains a concern.

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